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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,762	01/29/2004	David V. Dunsmore	TAL:8460.0002	7042

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EXAMINER	
BALDWIN, GORDON	
ART UNIT	**PAPER NUMBER**
1775	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,762	DUNSMORE ET AL.	
	Examiner	Art Unit	
	Gordon R. Baldwin	1775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050613*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Claim number 23 does not exist; appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 17 contain the trademark/trade name ASTM-75, ASTM-F-75, ASTM-799. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe a cobalt and chromium alloy and, accordingly, the identification/description is indefinite.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the polymer is structurally related to the article. Is the polymer another article that interacts or articulates with the body?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Shetty (Pat. No. 5,308,412).

Consider claim 1, 10, 11, 16 and 17, Shetty teaches a method of surface hardening a cobalt-chromium based implant device. However, the term "cobalt-chromium material" is also taught to included a cobalt-chromium-molybdenum alloy, which includes ASTM F-75 and ASTM F-799. (Col. 3 lines 55-70) The implant device is taught to have a hardening process in which a layer of chromium nitride is attached to the surface of the metal alloy ((Col. 2 lines 64-70-Col. 3 lines 1-5 and Col. 7 lines 55-65). Additionally, the medical device of a cobalt-chromium material is placed in a nitrogen gas process with pressure applied at a temperature of 500-2400 degrees Fahrenheit to form a CrN layer as the surface layer. (Col. 5 lines 51-60 and claim 1)

Consider claims 2, 3, 7, 8, 13 and 14, Shetty teaches that the layer of CrN is to have a thickness as low as .2 microns (2000 angstroms) to .5 microns (5000 angstroms (Table II)) as well as Shetty teaching that the layer is to be limited to a thickness of less than 100 microns, which is considered to encompass 3-15 microns. (Col. 7 lines 55-60)

Consider claims 4, 9 and 15, Shetty teaches a similar method of producing a CrN layer. (Col. 5 lines 1-65) However, Shetty does not specifically teach the formation of a transition layer being disposed on the CrN layer after the heat treatment. Since both of the procedures involve the same steps with the same materials, Shetty is also considered to teach the forming of a transition layer that is thinner than the surface layer. Additionally, it has been held that where the claimed and prior art products are identical or substantially identical in structure or are produced by identical or a substantially identical processes, a prima facie case of either anticipation or obviousness will be considered to have been established over functional limitations that stem from the claimed structure. *In re Best*, 195 USPQ 430, 433 (CCPA 1977), *In re Spada,* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The ***prima facie*** case can be rebutted by evidence showing that the prior art products do not necessarily posses the characteristics of the claimed products. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Consider claim 5, Shetty teaches that the coating is for orthopedic implants (Col. 1 lines 5-12), which are considered to be load-bearing, therefore any surface that is placed on the implant is also considered to be load bearing. (Col. 8 lines 12-19)

Consider claim 6, Shetty teaches a first surface that can be made of a polymer, (which is considered to include polyethylene as shown by its use, Col. 7 lines 20-25) with a body composed of a cobalt-chromium based implant device with a hardening process in which a layer of chromium nitride is attached to the surface of the metal alloy (Col. 2 lines 64-70-Col. 3 lines 1-5 and Col. 7 lines 55-65).

Consider claims 12, 18, 19, 20, 21, 22, 24 and 26, these claims are all considered to be product-by-process limitations and "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.", (In re Thorpe, 227 USPQ 964,966). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious different between the claimed product and the prior art product (*In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983), MPEP 2113).

Consider claim 25, Shetty teaches a method of surface hardening a cobalt-chromium based implant device. However, the term "cobalt-chromium material" is also taught to include a cobalt-chromium-molybdenum alloy. (Col. 3 lines 55-70) The implant device is taught to have a hardening process in which a layer of chromium nitride is attached to the surface of the metal alloy ((Col. 2 lines 64-70-Col. 3 lines 1-5

and Col. 7 lines 55-65). Additionally, Shetty teaches that the layer of CrN is to be in a thickness as low as .2 microns (2000 angstroms) to .5 microns (5000 angstroms (Table II)) as well as Shetty teaching that the layer is to be limited to a thickness of less than 100 microns, which is considered to encompass 3-15 microns. (Col. 7 lines 55-60)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3, 7, 8, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty (Pat. No. 5,308,412).

Consider claims 2, 3, 7, 8, 13 and 14, Shetty teaches that the layer of CrN is to have a thickness as low as .2 microns (2000 angstroms) to .5 microns (5000 angstroms (Table II)) as well as Shetty teaching that the layer is to be limited to a thickness of less than 100 microns, which is considered to mean that the coating only has to be less than 100 microns thick. (Col. 7 lines 55-60) Shetty does not teach the exact same proportions as recited in the instant claims.

However, one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Shetty overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious

to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

> "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In re Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Conclusion:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon R. Baldwin whose telephone number is (571)272-5166. The examiner can normally be reached on M-F 7:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GRB

JENNIFER MCNEIL
SUPERVISORY PATENT EXAMINER
10/30/06